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**REMARKS**

The Office Action dated August 11, 2006 has been received and reviewed. This response, submitted along with a Request for Continued Examination and a Petition for a Three-Month Extension of Time, is directed to that action.

Claims 1 and 18 have been amended. Claim 82, and 85-87 have been cancelled. Support for the amendments to claim 1 can be found throughout the specification, and specifically in Examples 1 through 9 and Figures 1 through 12. The amendment to claim 18 is formal in nature, and merely provides antecedent support for a claim element. No new matter is believed to have been added.

The applicants respectfully request reconsideration based on the foregoing amendments and the following remarks.

**Claim Rejections- 35 U.S.C. §112**

The Examiner rejected claims 1-2, 17-18, 21, 25-27, 78, 82 and 85-87 under 35 U.S.C. §112, first paragraph as not being enabled by the specification. The applicants submit that claim 1, as currently amended, and all claims which depend there from, are fully enabled by the specification.

The applicants respectfully submit that claim 2 is fully enabled by the description, as it is certainly within the knowledge of one of ordinary skill in the art to understand that chronic or acute heart failure can be caused by any of the conditions recited in this claim. Furthermore, the same holds true of claims 17 and 18. With respect to claims 25-27, the applicants respectfully submit that it is well within the knowledge of one of ordinary skill in

the art that ursodeoxycholic acid can be administered according to these claims, and does not require undue experimentation to determine if this method is effective. Accordingly, the present claims are enabled by the specification, and the applicants respectfully request that the Examiner withdraw this rejection.

The Examiner also rejected claim 1 under 35 U.S.C. §112, first paragraph as indefinite for stating "ursodeoxycholic acid and ursodeoxycholic acid in combination with diuretics". The present amendment replaces "and" with "or", thus obviating this rejection.

Claim Rejections- 35 U.S.C. §103

The Examiner rejected claim 1, 17, 18 25-27 and 78 under 35 U.S.C. §103(a) as obvious over US 5,674,855 in view of Niebauer et al. and Gennaro et al. The Examiner stated that the '855 patent teaches a method for treating endotoxin LPS mediated immune activation such as TNF- $\alpha$  production by administering ursodeoxycholic acid. The Examiner further stated that claim 1 differs only in that the patient is a human with acute or chronic heart failure and the ursodeoxycholic acid can be administered alone or with a diuretic. Niebauer teaches that abnormal levels of endotoxin are found in patients with heart failure. Gennaro teaches generally about different methods of administering pharmaceuticals. Accordingly, the Examiner concluded, it would have been obvious to administer ursodeoxycholic acid alone or in combination with a diuretic to a patient with acute or chronic heart failure based on the teachings of the '855 patent in view of Niebauer and further in view of Gennaro. The Examiner also rejected claims 21, 82 and 85-87 under 35 U.S.C. §103(a) as obvious over the '855 patent in view of Niebauer and Gennaro et al, and further in view of Schwarzenberg. The applicants respectfully traverse these rejections.

The applicants respectfully submit Niebauer et al. is not prior art against the present claims, and therefore is improperly cited. The present invention was filed as a 35 U.S.C. 371 application of PCT/EP00/02299, filed on March 9, 2000, which International application claimed priority to a series of applications filed in Great Britain on March 9, 1999 (Apps Nos. 9905315.9; 9905300.1; 9905310.0; 9905307.6; and 9905314.2). As Niebauer et al (Abstract from 71<sup>st</sup> Scientific Sessions of the American Heart Association; The Lancet, Vol. 353, May 29, 1999) was published on May 29, 1999, almost three months *after* the 35 U.S.C. §119 priority date of the present invention. Although certified copies of the priority documents are not believed to have yet been submitted to the USPTO, applicants will intend to do so in order to perfect the priority claim after receipt from the Great Britain Patent Office.

Because Niebauer et al. cannot be properly cited against the present claims, a *prima facie* case of obviousness cannot be established. Accordingly, the applicants respectfully request that these rejections be withdrawn.

Based on the amendments and remarks presented above, applicants respectfully request that the Examiner withdraw the rejections and allow this case to proceed to issue. If any issues remain, the resolution of which may be advanced through a telephone conference, the Examiner is invited to contact the applicant's attorney at the number listed below.

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FEB 12 2007**CONDITIONAL PETITION FOR EXTENSION OF TIME**

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefore. The Assistant Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

**ADDITIONAL FEE**

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

Respectfully submitted,

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